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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,284	04/09/2004	Bradley Moore	DEP5292	1111

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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05/13/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/821,284	Applicant(s) MOORE ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In view of the Appeal Brief filed on 10/22/2009, PROSECUTION IS HEREBY REOPENED. Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Claim Objections

Claims 40-41 and 44-46 are objected to because of the following informalities:

In claims 40 and 41, "a second pathway" should be changed to "the second pathway" since the claim limitation "a second pathway" first appears in a preceding claim (claim 39).

Claim 44 recites "the first pathway," however; this appears to be the first recitation of the claim limitation "the first pathway" and should be changed to "a first pathway". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (US 2003/0208203) in view of Chin (US 2005/0065517, see Provisional Application 60518580) and Shluzas (US 20040230100).

Lim et al. disclose a minimally invasive surgical method comprising making a first incision in a patient; inserting a retractor (130, para. [0049]) and expanding it, advancing a first anchor (120) through via the expanded retractor to a first anchor site on a first vertebra; and advancing a second anchor (121) through the expanded retractor to a second anchor site on a second vertebra adjacent the first vertebra. Lim further discloses positioning a first end of a spinal rod (200) in the expanded retractor; advancing the first end of the spinal rod subcutaneously; and coupling the spinal rod to the first anchor and the second anchor. Disk material is removed from the disk space between the first and second vertebrae through the first pathway, the method further

comprising inserting an interbody fusion device into the disk space (para [0039]). The retractor has an opening that allows the rod to pass through it.

Lim et al. disclose the claimed invention except for the steps of 1.) making a percutaneous incision in the patient and creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod subcutaneously/subfascially to the third anchor; and advancing a closure mechanism through the lumen of the percutaneous access device; and further comprising a second rod, and a fourth, fifth, and a sixth anchor, and 2.) the retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades.

Chin discloses making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod subcutaneously/subfascially to the third anchor; to perform minimally invasive surgery. (It is noted that the Chin method represents an improvement over the Lim et al. method. The incisions required by Chin are much smaller, and are therefore less invasive, and would be especially useful in surgeries spanning larger areas (for example, in surgeries where more than three bone anchors are used on each side of the spine).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Lim et al. making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device (see FIGS. 2a-b) having an opening to facilitate coupling to the rod element, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the rod element subcutaneously/subfascially to the third anchor (See FIG. 9); and advancing a closure mechanism through the lumen of the percutaneous access device in view of Chin to perform minimally invasive surgery where more than two anchors are being used. Chin would allow installation of many bone anchors (more than just the two anchors as disclosed in Lim et al.) without requiring a long incision or multiple larger incisions for multiple expandable retractor blades, while still maintaining a larger working space inside the body in which the surgeon could more easily initially insert a less flexible spinal rod before passing it through the body percutaneously. Moreover, the method of Lim et al. for insertion of the rod through the expandable retractor might be desirable to surgeons already trained on and familiar with the tools of Lim et al. used to insert the rod through the larger expandable retractor blades; surgeons might be slow to use the less familiar tools needed in Chin to insert a flexible spinal rod through the narrow insertion cannula, even while recognizing the benefit provided by passing the spinal rod under the skin as taught by Chin.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Lim in view of Chin using a second rod,

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and a fourth, fifth, and a sixth anchor (a second system on the opposite side of the spine), since it has been held that mere duplication involves only routine skill in the art.

St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

2.) Shluzas disclose using a retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades (paragraph [0145], see FIG. 12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Lim with a retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades in view of Shluzas, since such is a functional equivalent of the single blade expandable retractor disclosed in Lim et al. and would provide the same predictable result of allowing access into a working space within the body.

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (US 2003/0208203) in view of Chin (US 2005/0065517, see Provisional Application 60518580) and Shluzas (US 20040230100) further in view of Pagliuca et al. (US 2003/0073998).

Lim et al. in view of Chin and Shluzas disclose the claimed method except for removing disk material and inserting bone graft/an interbody fusion device into the disc space.

Pagliuca discloses removing disc material and inserting bone graft material/an interbody fusion in conjunction with a spinal anchoring system (FIG. 70, claim 14) to correct some spinal problems.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Lim et al. in view of Chin and Shluzas including removing disc material and inserting bone graft material/an interbody fusion device into the disc space in view of Pagliuca to better correct some spinal problems

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733